OPERATOR MANUAL

Castle®

BIOSIGN INCUBATORS 55° C-STEAM 37° C-EO

Getinge/Castle, Inc.
1777 East Henrietta Road
Rochester, New York 14623-3133
Phone: (800) 950-9912 U S A
Facsimile: (800) 950-2570

GETINGE Castle

OPERATOR MANUAL 350546
Rev. A (05/13/94) New Manual Release
Rev. B (02/26/97) Company name changed to Getinge/Castle, Inc.
Rev. C (11/14/97) Part numbers for final assembly changed

Related Publications:

Service Manual	350549
Parts Catalog	350567

DESCRIPTION OF SYMBOLS AND NOTES IN MANUAL

The following symbols with related notes appear in this manual.

"Warning" notes alert the user to the possibility of personal injury.

"Caution" notes alert the user to the possibility of damage to the equipment.

"Notes" alert the user to pertinent facts and conditions.

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IMPORTANT

SPECIAL SAFETY INSTRUCTIONS THAT FOLLOW APPEAR WITHIN THE MANUAL.
READ THEM CAREFULLY BEFORE OPERATING THE UNIT AND FOLLOW INSTRUCTIONS.

WARNING notes alert the user to a possibility of personal injury.

IMPORTANT

LES INSTRUCTIONS SPECIALES DE SECURITE SUIVANTES APPARAISSENT DANS LE MANUEL. LISEZ-LES ATTENTIVEMENT AVANT D'UTILISER LE MATERIEL ET CONFORMEZ-VOUS STRICTEMENT.

DANGER *alerte à l'utilisateur à la possibilité de blessure.*

THERMOMETER COLUMN SEPARATION 4

WARNING — Freezing hazard. The dry ice/methanol solution is at approximately -72°C (-98°F). Avoid spills. Contact with skin could injure the tissue.

WARNING — Flammable liquid. Methanol is flammable. Keep the solution and its vapors away from open flame.

BROKEN THERMOMETER 5

WARNING — The thermometer contains mercury, a U.S. Government classified hazardous material. Inhalation of mercury vapor can cause kidney and central nervous system damage varying upon the level of acute or chronic exposure. If broken, the thermometer must be disposed of in accordance with applicable laws and regulations.

LOADING THE INCUBATOR 6

WARNING — Biological Indicator (BI) vial may burst if crushed when hot. Do not crush the ampule until the BI is cool. Let the BI cool for 15 minutes outside the sterilizer. Failure to cool may result in personal injury.

WARNING — HOT SURFACE! Avoid contact with the block. Contact could cause burns.

CLEANING 7

WARNING — Unplug the unit before cleaning. Do not fully immerse the unit.

COLONNE DE SÉPARATION DU THERMOMÈTRE 4

AVERTISSEMENT — Danger d'engelure. La température de la solution de glace sèche et de méthanol est d'environ -72°C (98°F). Éviter les renversements. Le contact avec la peau peut en endommager les tissus.

Liquide inflammable. Le méthanol est inflammable. Garder la solution ainsi que ses vapeurs à l'abri de la flamme nue.

THERMOMÈTRE CASSÉ 5

AVERTISSEMENT — Ce thermomètre contient du mercure; cette substance est classée dangereuse par le Gouvernement Américain. L'inhalation des vapeurs de mercure peut causer des dommages variés aux reins et au système nerveux central dépendant si le niveau d'exposition est aiguë ou chronique. En cas de bris, on devra disposer du thermomètre en respectant les lois et règlements applicables.

CHARGER L'INCUBATEUR 6

AVERTISSEMENT — L'indicateur biologique (BI) peut éclater si on l'écrase quand il est chaud. Ne pas presser l'ampoule tant qu'il n'est pas refroidi. Sortir le BI du stérilisateur et laisser refroidir pendant 15 minutes. Un refroidissement insuffisant peut être la cause de blessures.

AVERTISSEMENT — SURFACE CHAUDE! Evitez tout contact avec le block chauffant. Danger de brûlures.

NETTOYAGE 7

AVERTISSEMENT — Débrancher l'appareil avant de nettoyer. Ne pas immerger l'appareil complètement.

INTRODUCTION

PROPRIETARY NAME

BIOSIGN incubator

GENERIC NAME

Microbiological incubator

MODEL IDENTIFICATION

Part No.	Volt	Temperature
61301600054 (531079)	120	37°C—EO
61301600055 (531080)	120	55°C—Steam
61301601608 (531081)	220–240	37°C—EO
61301601609 (531082)	220–240	55°C—Steam

INTENDED USE

To provide a controlled dry heat environment for incubation of BIOSIGN biological sterilization indicators (BIs).

The BIOSIGN incubators are factory preset. The 37°C incubator is intended for BIs used to monitor the ethylene oxide gas sterilization process. The 55°C incubator is intended for BIs used to monitor steam sterilization.

FUNCTION

To provide a controlled dry heat environment for incubation of BIOSIGN Biological Indicators (BIs) at 37°C or 55°C.

Each well is designed to activate the BIs by compressing the BIOSIGN outer vial to break the inner ampule of media. The array of wells provides a clear view of all incubating BIs, so that the user can quickly identify color-positive or color-negative BIs.

PRINCIPLES OF OPERATION

The basic incubator components are a block with twenty-one wells; elements; sensor; electronic controller board; thermometer; case; and cover. The heating circuit consists of a thermistor sensor centrally mounted in the block. The thermistor resistance signal is monitored by the control circuit, which compares the signal with a potentiometric setting. The control circuit allocates energy as needed to maintain the setpoint temperature. Temperature is indicated by mounting the supplied thermometer in the thermometer well. The conductive heat path is from element to block to well to BI vial to media.

The wells are precisely machined to maximize the contact of the BI vial with the block. The incubator cover promotes temperature uniformity and stability.

Each well is also designed to compress the BIOSIGN vial wall as it is inserted, to break the inner media ampule, thereby activating the BI. To do this, the vial bottom is inserted into the well and the body pivoted upward to seat the vial in the well and to activate the BI at the same time.

PERFORMANCE CHARACTERISTICS AND SPECIFICATIONS

TEMPERATURE SETTINGS

Model	Factory-Set Temperature	Uniformity	Stability	Biosign Vial Capacity	Unloaded Heatup Time (Minutes)	Temperature Stabilization Time After Reaching Setpoint (Minutes)
61301600054 (531079)	37±1°C	0.4°C	0.1°C	21	15	15
61301600055 (531080)	55±1°C	0.9°C	0.3°C	21	60	30
61301601608 (531081)	37±1°C	0.4°C	0.1°C	21	15	15
61301601609 (531082)	55±1°C	0.9°C	0.3°C	21	60	30

ELECTRICAL RATINGS

Model	Volts	AMP	Watts	Hz	Phase	Listing
61301600054 (531079)	120	0.4	48	50/60	1	UL/CSA
61301600055 (531080	120	0.4	48	50/60	1	UL/CSA
61301601608 (531081)	220–240	0.2	48	50/60	1	
61301601609 (531082)	220–240	0.2	48	50/60	1	

TECHNICAL DATA

Ambient Operating Range . . . . . 17–27°C (64–80°F)

Temperature . . . . . Field adjustable

Service Rating . . . . . Continuous operation

Dimensions, in (mm) . . . . . 7.6 (194) W x 9.4 (240) H x 6.0 (152) D

Relative Humidity Operating Range . . . . . 20–80% non-condensing

Thermometer Specifications

- Range . . . . . 10–60°C
- Degree Gradations . . . . . 1°C
- Highlight . . . . . 37° & 55°C
- Length, in (mm) 3 (76)

UNPACKING

Each carton contains the following items:

1 BIOSIGN Incubator

1 Thermometer, highlighted at 37°C and 55°C, with Certificate of Calibration

(The thermometer is mounted for shipment under a bracket on the rear cover.)

1 *Owner and Operator Manual*

Inspect your incubator to ensure the unit has not been damaged during transit. File a claim with the delivering carrier if the unit is received in a damaged condition. Retain all packing material.

PRECAUTIONS AND LIMITATIONS

1. Do not place the incubator near open windows, heating or cooling vents, or drafty areas.
2. Use only BIOSIGN BIs in your incubator. The wells are designed to fit the BIOSIGN vial.
3. Place the incubator in a well-lighted area. The polished wells reflect light into the BIs, making color changes more vivid.
4. Always incubate with the cover closed. The cover must be closed for the unit to meet specifications.

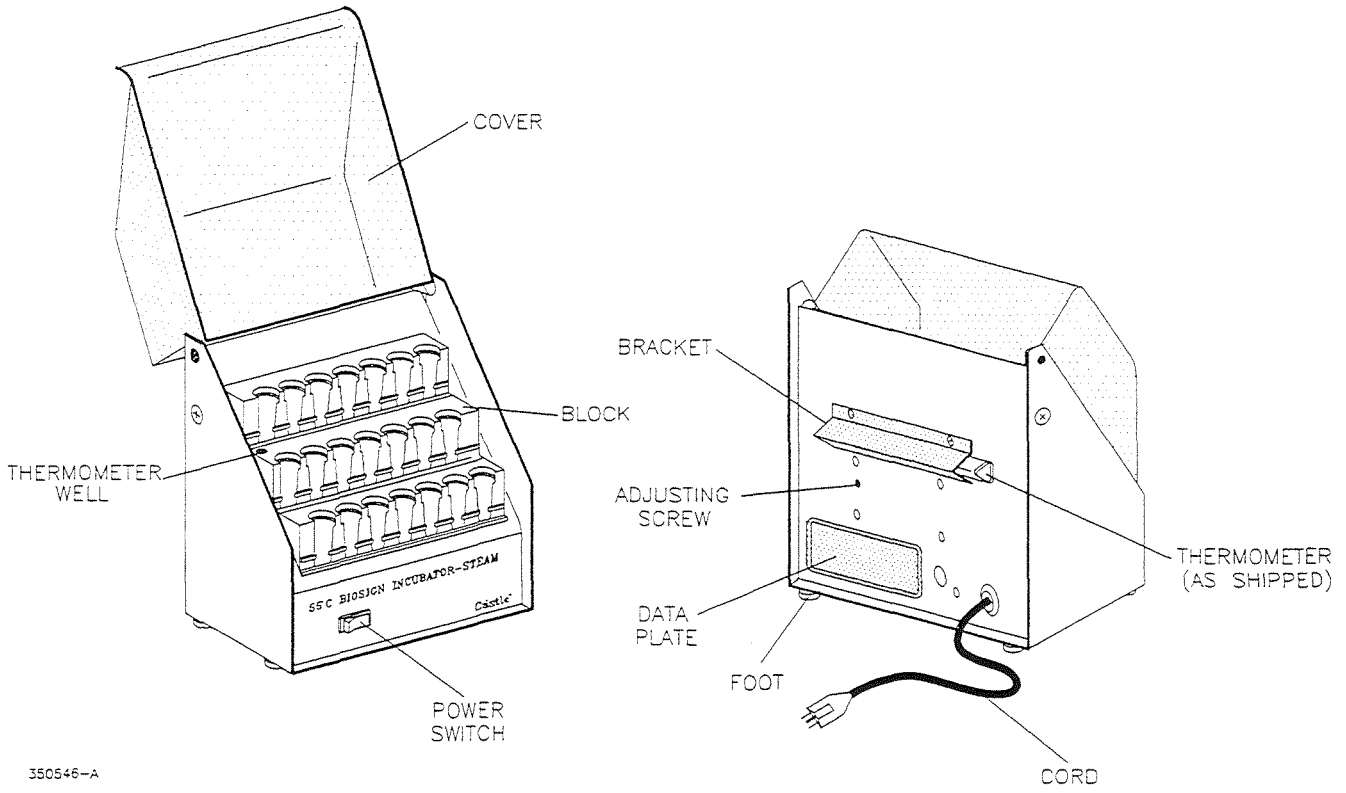

FIGURE 1. INCUBATOR FEATURES

SETUP AND CHECKOUT

SETUP

1. Locate your incubator in a draft-free, temperature-stable area.
2. Read the information on the data plate located on the rear of the unit (see Figure 1). Find the specified grounded receptacle into which to connect your incubator.
3. For shipment, the thermometer is mounted under a bracket on the rear cover of the incubator. Install the thermometer as follows.
   a. Loosen the bracket screws and slide the encased thermometer from the bracket.
   b. Remove the thermometer from the case. Remove the cap from the thermometer bulb.

NOTE

The thermometer includes a NIST-traceable Certificate of Calibration, which contains the serial number and the NIST (National Institute of Standards and Technology) identification number.

   c. Inspect the thermometer to ensure that the mercury column has not separated during shipment.

      If it has separated, rejoin the mercury column (see next page, "Thermometer Column Separation").

      If the thermometer is broken, see next page, "Broken Thermometer."

   d. Mount the thermometer in its well.
   e. File the Certificate of Calibration.
4. Place the unit on a smooth surface. Anchor the unit in position using the suction cup feet (see Figure 2).

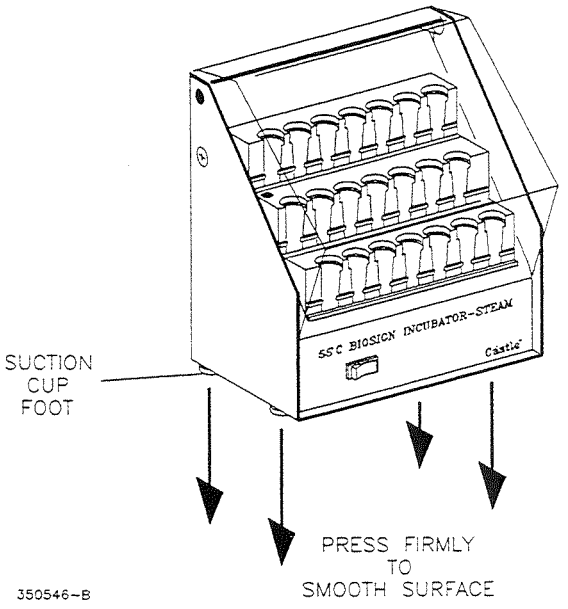

FIGURE 2. ANCHOR THE UNIT

THERMOMETER COLUMN SEPARATION

If the mercury column has separated, reunite it as follows.

- *Freezing hazard. The dry ice/methanol solution is at approximately –72°C (–98°F). Avoid spills. Contact with skin could injure the tissue.*
- *Flammable liquid. Methanol is flammable. Keep the solution and its vapors away from open flame.*

- *Do not touch the bulb until it has warmed enough for the mercury to emerge from the bulb into the capillary. Otherwise the bulb could break.*
- *Do not expose the stem or mercury column to the CO_2 solution. This will freeze the mercury column in the capillary and may cause the bulb to break.*

1. Prepare a solution of solid CO_2 (dry ice) and methanol.
2. With the thermometer upright, gradually immerse ONLY THE BULB in the dry ice solution. Do not allow the solution to touch the stem above the bulb.
3. Do not cool the stem or the mercury column.
4. The mercury will retreat slowly into the bulb.
5. Keep the bulb in the solution until all the mercury has retreated into the bulb.
6. Remove the bulb from the solution and swing the thermometer in a short arc, forcing any remaining mercury into the bulb.
7. Let the thermometer warm to room temperature. The mercury column will emerge reunited.

If you are not able to perform this procedure, or if it is unsuccessful, call Getinge/Castle, Inc., to arrange for a replacement thermometer at (800) 950–9912.

BROKEN THERMOMETER

The thermometer contains mercury, a U.S. Government classified hazardous material. Inhalation of mercury vapor can cause kidney and central nervous system damage varying upon the level of acute or chronic exposure. If broken, the thermometer must be disposed of in accordance with applicable laws and regulations.

For further details on spill response and waste disposal, refer to the Material Safety Data Sheet for mercury, available from Getinge/Castle, Inc., at (800) 950–9912.

CHECKOUT

1. Plug the incubator cord into the appropriate grounded receptacle.
2. Turn ON the power switch. It will light.
3. Wait until the thermometer gives a stable reading at the specified operating temperature (37°C or 55°C).
4. The incubator is ready for loading.

OPERATION

LOADING THE INCUBATOR

NOTE

For detailed instructions on the BIOSIGN biological indicator, refer to instruction sheet no. 350155 supplied with the indicator.

Each BIOSIGN vial contains a glass ampule containing media. The ampule is broken to release the media and thus activate existing bacterial growth. Each incubator well is designed to compress the vial walls to crush the glass ampule. Use the following procedure to activate each BIOSIGN vial.

WARNING

Biological Indicator (BI) vial may burst if crushed when hot. Do not crush the ampule until the BI is cool. Let the BI cool for 15 minutes outside the sterilizer. Failure to cool may result in personal injury.

1. Allow the biological indicators to cool at least 15 minutes, until the ampule cools to room temperature. Then snap the cap closed to seat uniformly against the collar (see Figure 3).

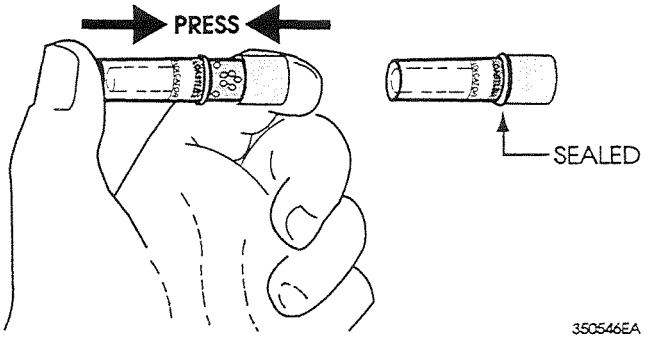

FIGURE 3. SEALING THE BIOLOGICAL INDICATOR.

2. Be sure the incubator is ON and at the specified operating temperature.
3. Open the incubator cover.

WARNING

HOT SURFACE! Avoid contact with the block. Contact could cause burns.

4. Insert the bottom of the BI into an empty well of the incubator (see Figure 4). Be sure the bottom of the vial contacts the base of the well.

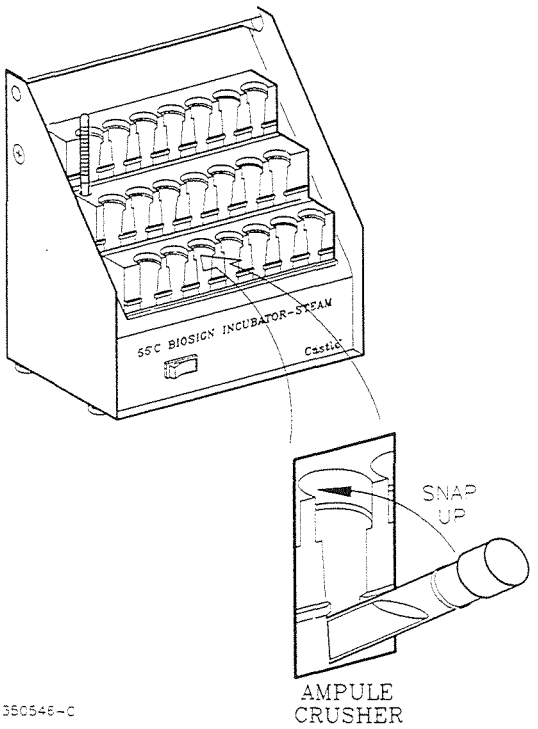

FIGURE 4. LOADING THE INCUBATOR

5. Pivot the BI up and into the well, so that the edges of the well crush the ampule.
6. Perform steps 4–5 for each BI.
7. Close the cover.

INCUBATING THE LOAD

1. Be sure that the incubator remains plugged in and ON throughout the entire incubating cycle.
2. View the BIs without opening the transparent cover. All BIs are visible, permitting quick identification of positives (yellow) or negatives (red).
3. Leave the incubator ON throughout the work period. Each time the unit is turned OFF and ON again, it takes time to stabilize at the incubation temperature. This can delay the processing time.

CLEANING

Unplug the unit before cleaning.
Do not fully immerse the unit.

Clean the incubator with a soft cloth, dampened with a domestic non-abrasive liquid cleaner suitable for glass and plastic.

CALIBRATION

Use the two procedures below to ensure that the incubator is operating at the proper temperature.

- To check that the incubator is operating at the proper temperature, perform "Verification of Calibration."
- If the incubator is not operating at the proper temperature, perform "Recalibration."

The thermometer supplied with the incubator is a NIST (National Institute of Standards and Technology) traceable thermometer.

VERIFICATION OF CALIBRATION

Equipment Required

- BIOSIGN incubator
- NIST traceable complete immersion thermometer (supplied with incubator)

Procedure

1. Turn on the incubator. Insert the thermometer into the thermometer well. Close the cover.
2. Wait until the thermometer gives a stable reading. This should be at the specified operating temperature (either 37°C or 55°C, marked on the incubator). Refer to Heatup Times under "Temperature Settings," page 2.
3. Read the temperature on the thermometer. Record it.
4. Compare the reading to the specified operating temperature.
   - If they are within 1°C, the incubator is properly calibrated.
   - If they are NOT within 1°C, recalibrate the incubator. Use "Recalibration" on next page.

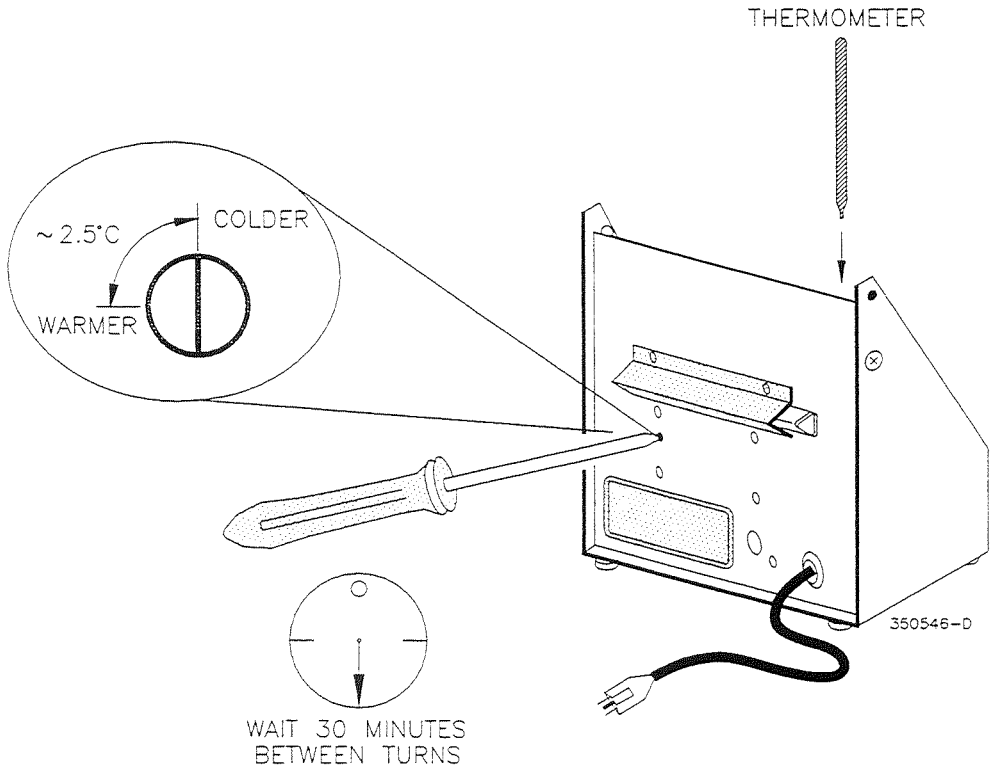

FIGURE 5. RECALIBRATING THE INCUBATOR

RECALIBRATION

Equipment Required

- BIOSIGN incubator
- NIST traceable complete immersion thermometer (supplied with incubator)
- Small, flat-bladed screwdriver

Procedure

1. Perform "Verification of Calibration" (previous page). If necessary to recalibrate, go to Step 2.
2. Adjust the temperature of the incubator (see Figure 5):
   a. Using a small, flat-bladed screwdriver, turn the adjusting screw.
      - To decrease temperature, turn the screw clockwise.
      - To increase temperature, turn the screw counterclockwise.
      - 1/4 turn equals approximately 2.5°C.
   b. Wait 30 minutes.
   c. Continue to wait until the thermometer gives a stable reading. This should be at the specified operating temperature (either 37°C or 55°C, marked on the incubator).
   d. Read the temperature on the thermometer. Record it.
   e. Compare the reading to the specified operating temperature.
      - If they are within 1°C, the incubator is properly calibrated. Turn OFF the incubator.
      - If they are NOT within 1°C, go to f.
   f. Repeat steps a–e until the thermometer reading is within 1°C of the specified operating temperature.

TROUBLESHOOTING GUIDE

Problem	Probable Cause	Solution
Erratic Temperature	Line-noise interference.	Plug into clean circuit.
	Plug not properly seated in receptacle.	Secure plug.
	Defective component.	Return for service.
Will not heat	Plug not seated properly.	Secure plug.
	Fuse or circuit breaker open in power service.	Replace fuse, reset breaker.
	Circuit connection open.	Inspect and reconnect.
	Element circuit open.	Return for service.
	Power switch malfunction.	Return for service.
Thermal Runaway	Line noise interference.	Plug into a clean line.
	Component failure.	Return for service.

WARRANTY

Getinge/Castle, Inc., warrants this incubator to be free from defects in material and workmanship for a period of one year from date of purchase. Getinge/Castle, Inc., will repair or replace defective units, at its option.

This warranty applies only to defects in original parts or components and does not apply to claims or alleged product failures resulting from unauthorized repairs, misuse, accidents, or lack of proper maintenance, failure to follow Getinge/Castle, Inc.,'s instructions for use and/or from ordinary wear and tear.

Getinge/Castle, Inc., makes no warranty of fitness or merchantability and no other warranty, oral or written, express or implied, except as specifically set forth herein.

SERVICE

If your incubator requires repair, return it to:

Product Support Marketing
Getinge/Castle, Inc.
1777 East Henrietta Road
Rochester, New York 14623-3133

For units under warranty, see "Warranty" at left for terms. For units out of warranty, Getinge/Castle, Inc. will evaluate the unit, advise you of the cost of repair, and request approval to proceed.

A *Service Manual* (350549) and *Parts Catalog* (350567) can also be ordered from Getinge/Castle, Inc. at the above address.

Getinge/Castle, Inc.
1777 East Henrietta Road
Telephone (800) 950-9912 Rochester, New York 14623-3133 USA Facsimile (800) 950-2570